

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT**  
**FOR THE DISTRICT OF NEW JERSEY**

ACORDA THERAPEUTICS, INC.,

Plaintiff,

V.

APOTEX CORP., and APOTEX INC.,

Defendants.

Civil Action No. 07-4937 (JAG)

## OPINION

**GREENAWAY, JR., U.S.D.J.**

This matter comes before this Court on the motion by Defendants, Apotex Corp., and Apotex Inc., (collectively “Defendants” or “Apotex”), for judgment on the pleadings, pursuant to FED. R. CIV. P. 12(c), against Plaintiff, Acorda Therapeutics, Inc., (“Acorda”). For the reasons set forth below, Defendants’ motion is denied.

## I. BACKGROUND

Acorda, a Delaware corporation, specializes in the research, development, and sale of biotech and pharmaceutical products. (Plaintiff’s Complaint (“Compl.”), ¶ 1.) Apotex Corp., a Delaware corporation, is a wholly-owned subsidiary of Apotex Inc., a Canadian corporation. (Id., ¶¶ 2, 3.)

Acorda is the holder of New Drug Application (“NDA”) No. 02-1447 for tizanidine hydrochloride capsules, which the FDA approved on August 29, 2002. (*Id.*, ¶ 10.) Apotex Inc. filed an Abbreviated New Drug Application (“ANDA”), seeking approval to market generic tizanidine hydrochloride capsules. (Compl. ¶¶ 12, 13.)

Acorda brought this action alleging infringement of its patent, U.S. Patent No. 6,455,557 (“the ’557 patent”). Specifically, in its Complaint, Acorda alleges that Apotex “has infringed at least one claim of the ’557 patent by submitting, or causing to be submitted to the FDA ANDA No. 78-868 seeking approval for the commercial marketing of Apotex Inc.’s generic capsules before the expiration date of the ’557 patent.” (Compl. ¶ 15.) As part of its prayer for relief, Acorda petitions this Court to, “declare this to be an exceptional case<sup>1</sup> under 35 U.S.C. §§ 285 and 271(e)(4) and award Acorda costs, expenses and disbursements in this action, including reasonable attorney fees.” (Compl., prayer for relief at ¶ 4.) Defendants move for judgment on the pleadings, pursuant to Rule 12(c) of the Federal Rules of Civil Procedure to dismiss plaintiff’s prayer for relief, and seek a determination by this Court that the instant action does not constitute an “exceptional case.”

## II. STANDARD OF REVIEW

A motion for judgment on the pleadings, pursuant to FED. R. CIV. P. 12(c), may be filed after the defendant has filed an answer to the complaint. Mele v. Fed. Reserve Bank of N.Y.,

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<sup>1</sup>Under 35 U.S.C. § 285, “the [C]ourt in exceptional circumstances may award reasonable attorneys fees to the prevailing party.” Furthermore, 35 U.S.C. § 271(e)(4) specifically states that when infringement is based on the filing of an ANDA, “a court may award attorneys fees under Section 285.”

In typical patent infringement cases, the United States Court of Appeals for the Federal Circuit has found “exceptional cases” to be cases where there is evidence of misconduct, including “inequitable conduct before the PTO, litigation misconduct such as vexatious or unjustified litigation or frivolous filings, and willful infringement.” Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1350 (Fed. Cir. 2004) (citing Hoffmann-La Roche Inc. v. Invamed Inc., 213 F.3d 1359, 1365 (Fed. Cir. 2000); Rosemount, Inc. v. Beckman Instruments, Inc., 727 F.2d 1540, 1548 (Fed. Cir. 1984)).

359 F.3d 251, 253 n.1 (3d Cir. 2004).<sup>2</sup> The standard for a motion for judgment on the pleadings under FED. R. CIV. P. 12(c), is the same as that for a motion to dismiss under FED. R. CIV. P.

12(b). See Spruill v. Gillis, 372 F.3d 218, 223 (3d Cir. 2004) (“There is no material difference in the applicable legal standards.”).

A Rule 12(b)(6) motion to dismiss should be granted only if the plaintiff is unable to articulate “enough facts to state a claim to relief that is plausible on its face.” Twombly, 127 S. Ct. at 1974; see also In re Warfarin Sodium Antitrust Litig., 214 F.3d 395, 397 (3d Cir. 2000) (stating that a complaint should be dismissed only if the alleged facts, taken as true, fail to state a claim). “Federal Rule of Civil Procedure 8(a)(2) requires only ‘a short and plain statement of the claim showing that the pleader is entitled to relief,’ in order to ‘give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.’” Bell Atl. Corp. v. Twombly, 127 S. Ct. 1955, 1964 (2007) (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)). “While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” Twombly, 127 S. Ct. at 1964-65 (internal citations omitted); see also FED. R. CIV. P. 8(a)(2). “Factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact).” Id. at 1965 (internal citations omitted). “The pleader is required to ‘set forth sufficient information

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<sup>2</sup>Defendants have also moved pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Defendants answered the Complaint. Thus, the Complaint is properly challenged pursuant to Rule 12(c) of the Federal Rules of Civil Procedure. Nonetheless, the standard of review under either Rule is the same.

to outline the elements of his claim or to permit inferences to be drawn that these elements exist.” Kost v. Kozakewicz, 1 F.3d 176, 183 (3d Cir. 1993) (quoting 5A Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure Civil 2d § 1357 at 340) (2d ed. 1990).

A court must accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the non-moving party. Oshiver v. Levin, Fishbein, Sedran & Berman, 38 F.3d 1380, 1384-85 (3d Cir. 1994); see also Sturm v. Clark, 835 F.2d 1009, 1011 (3d Cir. 1987). The question is whether the claimant can prove any set of facts consistent with his or her allegations that will entitle him to relief, not whether that person will ultimately prevail. Semerenko v. Cendant Corp., 223 F.3d 165, 173 (3d Cir. 2000).

While a court will accept well-pled allegations as true for the purposes of the motion, it will not accept bald assertions, unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations. Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 n.8 (3d Cir. 1997). “The defendant bears the burden of showing that no claim has been presented.” Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005).

In reviewing a motion to dismiss, pursuant to Rule 12(b)(6), a court may consider the allegations of the complaint, as well as documents attached to or specifically referenced in the complaint, and matters of public record. Pittsburgh v. W. Penn Power Co., 147 F.3d 256, 259 (3d Cir. 1998); see also 5B Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure: Civil 3d § 1357 (3d ed. 2007).

### III. DISCUSSION

Apotex moves this Court, pursuant to 12(c) of the Federal Rules of Civil Procedure, to dismiss Plaintiff's prayer for relief that the instant case be found "exceptional". In support of its motion, Apotex directs the Court to the Federal Circuit's opinion in Glaxo Group Limited v. Apotex, Inc., 376 F.3d 1339 (Fed. Cir. 2004). There, the Federal Circuit held that "the mere filing of an ANDA cannot constitute grounds for a willful infringement determination" because such a filing merely creates "an *artificial* act of infringement for purposes of establishing jurisdiction in the federal courts...." Glaxo, 376 F.3d 1351-52 (emphasis in original); see also id. at 1350-51 ("[W]e now hold that the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e) (4).").

It is apparently Apotex's argument that Acorda's exceptional case prayer may not stand in the absence of a pleading of willful infringement.<sup>3</sup> (See, generally, Defendants' Brief in Support of its Motion for Judgment on the Pleadings.) The Glaxo holding, however, does not stand for such a proposition. The Federal Circuit has specifically held that "a patentee in a ANDA case can recover attorney fees for willful infringement/litigation misconduct under the appropriate circumstances." Yamanouchi Pharm. Corp. v. Danbury Pharm. Inc., 231 F.3d 1339, 1342 (3d Cir. 2000). Courts in this Circuit have interpreted the Federal Circuit's directive in both Glaxo and Yamanouchi to be that while an ANDA filing, alone, cannot form the basis of a

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<sup>3</sup>Defendants automatically dismiss the notion that Acorda can allege litigation misconduct because the instant action is still in its infancy. (Defendants' Reply Brief in Support of the Motion for Judgment on the Pleadings, pp. 5-6.) The crux of Defendants' argument is that Acorda cannot, as a matter of law, allege willful infringement solely based on Apotex's ANDA filing.

plaintiff's exceptional case claim, plaintiff is not precluded from later establishing such a claim with the addition of proof of other misconduct. See, e.g., Celgene Corp. v. Teva Pharms, USA, Inc., 412 F. Supp. 2d 439, 445 (D.N.J. 2006); see also Sepracor Inc. v. Dey, L.P., 2008 WL 4377570, at \*2-3 (D. Del. 2008) (striking willfulness allegation, but leaving prayer for relief for an exceptional case finding intact); Novartis Pharm. Corp. v. Teva Pharm. USA, Inc., 2005 WL 3664014, at \*2 (D.N.J. 2005)

Here, the instant action concerns a plaintiff that has taken the correct steps, in its prayer for relief, to preserve its right to seek a declaration that instant action is an exceptional case. Acorda's Complaint makes no mention of willfulness, in compliance with the Federal Circuit's holding in Glaxo that ANDA filings cannot, alone, sustain willfulness claims. The Complaint only mentions the exceptional case finding as a "prayer for relief." Apotex's argument that Plaintiff has not yet established a basis for an exceptional case finding is irrelevant. Under Federal Circuit case law, Plaintiff may pursue its exceptional case prayer for relief, at present.

### **III. CONCLUSION**

For the reasons stated above, Defendants' motion is denied.

Date: December 29, 2008

S/Joseph A. Greenaway, Jr.  
JOSEPH A. GREENAWAY, JR., U.S.D.J.